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In the Supreme Court of the United States

OCTOBER TERM, 1987

KEVAN BERKOVITZ, ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES

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QUESTION PRESENTED

Whether the discretionary function exception to the Federal Tort Claims Act, 28 U.S.C. 2680(a), bars petitioners' claims that the government was negligent in its 1963 decision to license production of the Sabin oral polio vaccine and in its subsequent approval of the release of a specific lot of that vaccine.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-27a) is reported at 822 F.2d 1322. The opinion of the district court (Pet. App. 28a-36a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on June 30, 1987. The petition for a writ of certiorari was filed on September 25, 1987, and was granted on January 11, 1988. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISION INVOLVED

28 U.S.C. 2680 provides, in pertinent part:

> The provisions of this chapter and section 1346(b) of this title shall not apply to—
>
> (a) Any claim * * * based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused.
>
> * * * * *

STATEMENT

Polio and the Sabin Vaccine

Prior to 1955, poliomyelitis was a major crippler of children in the United States and throughout the world. In 1952 alone, 57,879 cases of polio were reported in the United States, of which 21,269 cases resulted in crippling paralysis to the victims. See 77(12) *Pub. Health Rep.* 1011-1020 (1962).[1] The first major step in the eradication of polio came with the development of the Salk inactivated-virus vaccine, which was licensed in this country in 1955.[2] The Salk vaccine immediately regis-

[1] Polio is caused by an enterovirus that is introduced into the body orally and begins to reproduce rapidly in the intestinal tract. In only about one percent of cases will this original "infection" result in clinical symptoms of poliomyelitis. When the disease does result, it is caused by a spread of the virus from the intestinal tract to the brain and spinal column, where it causes damage to the nervous system, resulting in the characteristic muscular paralysis. See J. Melnick, *"Enteroviruses,"* in *Viral Infections of Humans* 217-218, 220 (A. Evans 2d ed. 1982).

[2] Salk vaccine is a killed virus vaccine produced by growing the virus in a tissue culture and killing it chemically to render it incapable of replicating and thereby causing disease, but capable of acting as an antigen to stimulate the production of antibodies. If a wild or virulent strain of poliovirus subsequently enters the body, the antibodies will block the live virus and prevent the contraction of polio. J. Melnick, *supra*, at 228.

tered great progress against the disease, but it was not a perfect solution. A 1962 Report of the Surgeon General recognized that "extensive use of the Salk-type, killed-virus vaccine during the past seven years has greatly lowered the incidence of paralytic disease but has not prevented either sporadic cases or occasional epidemics in highly-vaccinated communities." HEW, *Revised Recommendations and Report: The Surgeon General's Advisory Committee on Poliomyelitis Control* 1 (Feb. 17, 1962) [hereinafter *Surgeon General Report*]. After a record low of 2,499 cases of paralytic polio in 1957, the number of cases began to increase and had more than doubled to 6,289 in 1959. Moreover, data regarding antibody levels 2 to 4 years after inoculation with the Salk vaccine indicated that repeated, possibly frequent, booster shots would be required for an individual to retain immunity. *Report of Committee on Infectious Diseases*, Am. Acad. of Pediatrics 47 (1966) [hereinafter *Infectious Diseases Report*].

The second major breakthrough in combating the disease occurred with the development of the Sabin oral polio vaccine which was introduced here in the early 1960s. Unlike the Salk vaccine, the oral vaccine contains a weakened, but live, polio virus. The Sabin vaccine offered several advantages over the Salk vaccine. First, it induces effective, lasting immunization without need of subsequent booster shots. Second, it can be administered with comparative ease, since it is taken orally instead of by injection. Third, it protects against infection as well as disease, thereby insuring that infected persons would not become transmitters of the wild poliovirus. Finally, and of particular importance, the virus in the Sabin vaccine is also communicated to persons in close contact with the vaccinee. By this means, individuals not directly reached through the vaccination program nevertheless receive the benefits of immunization. See *Infectious Diseases Report* 47-48. Because of these advantages, the Sabin vaccine rapidly displaced the Salk vaccine in the

early 1960s. It became "the vaccine of choice for community-wide vaccination programs and for routine immunization in infancy and childhood" (*id.* at 48). See *Surgeon General Report* 1. By the mid-1970s, the total number of cases of paralytic polio reported in the United States had declined to approximately ten to twenty per year. See Center for Disease Control, 28(54) *Morbidity and Mortality Weekly Report* 12 (Nov. 16, 1984). Current figures reveal an annual average of ten cases. Nkowane & Wassilak, *et al.*, *Vaccine-Associated Paralytic Poliomyelitis, United States: 1973 Through 1984*, 257(10) J. Am. Med. A. 1335 (Mar. 13, 1987).

Despite this record of success, there has been continued debate over the relative merits of the Salk and Sabin vaccines. See, *e.g.*, Boffey, *Polio: Salk Challenges Safety of Sabin's Live-Virus Vaccine*, 196 Science 35 (1977). It has been determined that the Sabin vaccine creates a very slight risk that the vaccinee or someone in close contact with him will contract the disease.[3] No similar risk exists with the Salk vaccine, provided the virus used in the vaccine is successfully killed. After exhaustive study, however,[4] the

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[3] There is a very slight risk that paralytic poliomyelitis may be contracted by persons who ingest the Sabin oral polio vaccine, or by persons coming in close contact with the vaccinee. Between 1972 and 1983, 87 vaccine-associated cases in apparently immunologically normal individuals were reported. During that period, 278.8 million OPV (oral polio vaccine) doses were distributed in the United States. Thirty-two vaccine-associated cases of poliomyelitis occurred among vaccine recipients (one case per 8.7 million OPV doses distributed) and 55 cases occurred among household and non-household contacts of vaccinees (one case per 5.1 million doses distributed).

Center for Disease Control, 33(45) *Morbidity and Mortality Weekly Report: Paralytic Poliomyelitis—United States, 1982 and 1983*, at 637 (Nov. 16, 1984).

[4] See, *e.g.*, Nightengale, *Recommendations for a National Policy on Poliomyelitis Vaccination*, 297 New Eng. J. Med. 249-253 (1977)

United States remains firmly committed to the Sabin vaccine.[5]

Facts and Proceedings Below

1. Petitioner Kevan Berkovitz contracted polio in June 1979 shortly after receiving Orimune, a Sabin oral polio vaccine manufactured by Lederle Laboratories. Berkovitz, joined by his parents as guardians, filed suit in federal district court in December 1984 alleging that the United States was liable for his injuries under the Federal Tort Claims Act (FTCA) because the government was negligent in licensing Orimune on June 25, 1963, and because the Food and Drug Administration (FDA) was negligent in releasing the specific lot of vaccine from which Berkovitz received his dose on May 10, 1979 (Pet. App. 4a).[6] As to the first claim, petitioners alleged that the Division of Biologic Standards (DBS), at that time part of the National Institutes of Health, issued a license for Lederle's Sabin poliovirus strain when it had not been

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(reporting results of study by Institute of Medicine of the National Academy of Sciences commissioned by HEW); Center for Disease Control, 26(40) *Morbidity and Mortality Weekly Report: Recommendation of the Public Health Service Advisory Committee on Immunization Practices* 329 (Oct. 7, 1977); *id.* 31(3) *Morbidity and Mortality Weekly Report: 1982 ACIP Report* 22 (Jan. 29, 1982).

[5] Congress has actively promoted use of the Sabin vaccine since 1961 when it appropriated $1 million for a stockpile of the newly-developed vaccine to be used in combatting epidemics. Act of Mar. 31, 1961, Pub. L. No. 87-14, 75 Stat. 23. In the Vaccination Assistance Act of 1962 Congress launched mass immunization campaigns using the Sabin vaccine. Pub. L. No. 87-868, 76 Stat. 1155. Although Congress originally envisioned an intensive three-year effort, the need for ongoing federal support for immunization programs became apparent and continues to be provided through the Act, now codified at 42 U.S.C. 247b. All fifty states and the District of Columbia require vaccination before a child enters school.

[6] Petitioners also sued Lederle Laboratories in a separate civil action. That suit was settled shortly before the instant case was filed. Pet. App. 5a n.3. See *Berkovitz* v. *Lederle*, No. GD 80-28592 (Alleghany County C.P. Ct. filed Nov. 17, 1980). The terms of the settlement are under seal.

tested in accordance with DBS's own regulations, and that DBS failed to require Lederle to show that a particular "seed virus" had been subjected to all required testing and had complied with all regulatory standards. Br. 4-6; Pet. App. 4a-5a. On the second issue, petitioners claimed that the Bureau of Biologics of the FDA improperly issued a lot release approval, permitting the vaccine containing Berkovitz's dose to be distributed to the public, despite the fact that the virus in the vaccine had been tested and found to exceed the standards for neurovirulence set forth in regulations applicable to live polio vaccines. Br. 6-7, 20-21; Pet. App. 4a-5a.[7]

2. The government moved to dismiss the suit as barred by the discretionary function exception to the FTCA, 28 U.S.C. 2680(a). The district court (Pet. App. 28a-36a) agreed that the government was immune from two of petitioners' original claims,[8] but nonetheless concluded that both the licensing of Lederle to produce the vaccine and the release of the specific vaccine lot were not "discretionary function[s]" within the meaning of the FTCA (*id.* at 33a). The district court noted that the Third Circuit had already held in *Griffin v. United States*, 500 F.2d 1059 (1974), that negligent release of a noncomplying lot of polio vaccine was not a discretionary function. The government maintained in its motion to dismiss that *Griffin* had been effectively overruled by

[7] Petitioners also claimed in district court that the United States was negligent in failing to withdraw the vaccine from the market and in failing to require the manufacturer to provide adequate warnings. These allegations were dismissed in the district court as barred by the FTCA's "discretionary function" exception (Pet. App. 33a), and petitioners conceded the propriety of that dismissal on appeal (*id.* at 6a n.4). The petition for a writ of certiorari did not ask this Court to review those issues (see Pet. 3-5). Without acknowledging their prior concession, in their Brief on the Merits (at 6, 19-20) petitioners once again argue that the government is liable for failing to revoke Lederle's license and withdraw the vaccine from the market.

[8] See note 7, *supra*.

this Court's decision in *United States* v. *S.A. Empresa De Viacao Aerea Rio Grandense (Varig Airlines)*, 467 U.S. 797 (1984). The district court declined to consider the effect of *Varig Airlines*, however, noting that, as a reported decision of the Third Circuit, *Griffin* was binding on the district courts in that circuit "no matter how persuasive the arguments may be that *Griffin* is no longer valid" (Pet. App. 33a).

3. At the government's request, the district court certified its decision for immediate appeal to the Third Circuit pursuant to 28 U.S.C. 1292(b), which reversed in a divided opinion (Pet. App. 1a-27a). The court of appeals initially rejected the government's argument that the discretionary function exception bars all claims arising out of the regulatory activities of federal agencies (*id.* at 12a-15a). Concluding that it "need not treat separately the licensing claim and the lot release claim" (*id.* at 15a), the court then proceeded to analyze the question whether the government had a nondiscretionary duty to ensure that Lederle followed regulatory standards in the production and distribution of the Sabin polio vaccine (*ibid.*).

The court of appeals canvassed the applicable regulations and noted that, while they required the manufacturer to perform certain tests and submit qualifying results to the government, they did not require the government to do anything (Pet. App. 16a-18a). The court concluded that, as in *Varig Airlines*, the onus was on the manufacturer to comply with applicable safety standards, while the role of the government agency was "'merely to police the conduct of private individuals by monitoring their compliance with [the applicable] regulations'" (*id.* at 22a (quoting 467 U.S. at 815)). See Pet. App. 16a ("the safety regulations governing live polio vaccine leave at least as much enforcement discretion to the FDA as the regulations at issue in *Varig* left to the FAA").

The court of appeals also examined the statutory requirement that licenses may be issued "only upon a showing that * * * the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations" (42 U.S.C. 262(d)). The court rejected the dissent's contention that this statute created a nondiscretionary duty for the FDA "to 'insure' compliance with its safety regulations" (Pet. App. 18a).[9] "[T]he FDA's statutory duty," the court concluded, "is not different in substance from the duty that the Supreme Court in *Varig* found rests with the FAA" (*ibid.*). In both cases, the agency is left with a policy choice as to how to construct and implement a mechanism for compliance review. Because "neither the statute nor the regulations mandate the FDA's choice of how to secure Lederle's compliance" (*id.* at 22a), the court concluded that the discretionary function exception bars suit for alleged negligence in the government's performance of that role.

The court of appeals acknowledged that the allegations in this case differ from those in *Varig Airlines* in that petitioners here claimed that "the FDA exercised its discretion to verify compliance and then negligently erred in finding compliance" (Pet. App. 20a). Petitioners argued that "once the FDA had information that the vaccine did not comply with the regulations, it had no discretion to approve either the license for production or the

[9] Judge Higginbotham, in his dissenting opinion (Pet. App. 25a), argued that 42 U.S.C. 262(d) "creates a governmental duty not to license a manufacturer that has shown the government that its vaccine is defective." He compared the FDA's mandate with the statutes governing the FAA, which he said "are not commands at all." "Rather," the dissent argued (Pet. App. 26a (emphasis in original)), "they amount to requests for the prudent exercise of agency discretion, and they are *truly* different in substance from the statute that *prohibits* vaccine licensure by the government whenever the requisite showing has not been made."

lot for release" (*ibid.*). But the court noted that "this argument is simply that the FDA acted negligently" and "the issue of negligence is not relevant to the discretionary function inquiry" (*id.* at 21a (citation and quotation marks omitted)).

The FDA made a policy choice to attempt to monitor compliance by manufacturers more closely than the "spot-check" review conducted by FAA. But that policy choice does not subject an agency to liability for "negligently fail[ing] to recognize and remove noncomplying products" (Pet. App. 21a). An alternative holding, the court stated, "would inhibit the agency's selection of the mechanism for compliance review" and "[t]his is precisely what *Varig* instructs us not to do" (*ibid.*). "It follows," the court concluded, "that when the FDA makes the discretionary choice to examine or test samples which it has discretion not to test, it cannot be held liable for subsequent negligence at the operational level in implementing its decision to test" (*ibid.*).

SUMMARY OF ARGUMENT

The Food and Drug Administration (FDA) has a general mandate to construct and implement a licensing program for vaccines and other prescription drugs. Its role is two-fold: it fashions standards of safety, potency and purity that any such product must meet and it polices compliance with those standards through licensing and inspections. As with other regulatory programs, however, the primary burden of compliance with FDA regulations (and, consequently, any responsibility for noncompliance) rests upon the manufacturer. The FDA's activities as a policeman of private conduct are accordingly protected from suit by the discretionary function exception to the FTCA. As this Court noted in *Varig Airlines*, 467 U.S. at 821, regulatory agencies have "a statutory duty to *promote* safety" in the industries they regulate, "not to insure it."

Petitioners contend that when licensing and inspection activities are governed by mandatory regulations and an agency negligently violates its own regulations in issuing a license or conducting an inspection, the discretionary function exception does not apply. There are three related flaws in this argument. First, it ignores the wording of the discretionary function exception, which protects agency *functions*, not individual acts, and which precludes liability whether or not the government has acted negligently by breaching one of its own regulations. The FDA's "implementation of a mechanism for compliance review is plainly discretionary activity of the 'nature and quality' protected by § 2680(a)" (*Varig Airlines*, 467 U.S. at 819), and the discretionary function exception shields from liability "both negligence and wrongful acts in the exercise of discretion." *Dalehite* v. *United States*, 346 U.S. 15, 33 (1953). Second, it largely eliminates the protection of regulatory functions—thereby frustrating the prime motivation for the discretionary function exception—because tort claims can almost always be couched in terms of mandatory duties left unperformed. What was intended as a bar to suit would become merely a rule of pleading. Third, contrary to Congress's express intention, it interjects tort considerations into a regulatory agency's fundamental policy decision on how specifically to write its regulations (and, hence, how carefully to regulate private industry) by providing agencies with a strong incentive towards vagueness and a lack of guidelines for inspectors. "When an agency determines the extent to which it will supervise the safety procedures of private individuals, it is exercising discretionary regulatory authority of the most basic kind." *Varig Airlines*, 467 U.S. at 819-820.

As a general principle, therefore, safety-related licensing and inspection activities are shielded from suit by the discretionary function exception regardless of claims that the agency in question has violated its own regulations. In any event, petitioners are unsuccessful in their

attempt to portray the FDA's regulations as imposing mandatory duties on FDA employees. In fact, the burden of compliance in each instance cited by petitioners is placed squarely on the private manufacturer. The regulations require the manufacturer to perform certain tests and submit qualifying data to the FDA prior to using a particular seed virus in its vaccine or prior to releasing a lot of vaccine. But the regulations impose no duties on the FDA to perform any tests on its own; nor do the regulations indicate the extent to which FDA must review the data submitted to ensure compliance. A decision to redo certain tests or examine certain test results is clearly "discretionary regulatory authority of the most basic kind" (*Varig Airlines*, 467 U.S. at 820). Petitioners claim that the FDA performed this function negligently, thereby permitting release of a noncomplying lot; but clearly the discretionary function exception bars suit for alleged "negligence and wrongful acts in the exercise of the discretion" (*Dalehite*, 346 U.S. at 33). Thus, "when the FDA makes the discretionary choice to examine or test samples which it has discretion not to test, it cannot be held liable for subsequent negligence at the operational level in implementing its decision to test" (Pet. App. 21a).

The FDA has not been delegated any authority by Congress to turn itself into an insurer of the industry it regulates. Congress knows how to set up an insurance program for a regulated industry when it wants to, and when it does so the program looks very different from an ordinary regulatory scheme. We know that because in 1986 Congress passed just such a program in the National Childhood Vaccine Act of 1986. The Act establishes a National Vaccine Injury Compensation Program that is intended to provide an exclusive remedy for vaccine-related injuries. An essential premise of that program is that persons injured by vaccines have no tort remedy against the United States for licensing the vaccines. For the Court now to overlay this insurance scheme with tort liability under the FTCA would wholly

disrupt the compensation scheme in the Act as well as Congress's attempt to fund the program with a minimum drain on the public fisc.

ARGUMENT

THE DISCRETIONARY FUNCTION EXCEPTION TO THE FEDERAL TORT CLAIMS ACT BARS LIABILITY BASED ON THE ALLEGED NEGLIGENCE OF THE FDA IN CARRYING OUT ITS REGULATORY TASK OF LICENSING VACCINES AND OTHER DRUGS

No biological product "applicable to the prevention, treatment, or cure of diseases or injuries of man" may be sold in the United States that has not been "propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary [of Health and Human Services] as hereinafter authorized, to propagate or manufacture, and prepare such" product (42 U.S.C. 262(a)). This federal regulation of vaccines and other biological products for human use was first enacted in 1902, Act of July 1, 1902, ch. 1378, 32 Stat. 728, and later revised in 1944 as part of the recodification of the Public Health Service Act, ch. 373, § 351, 58 Stat. 702.

The Act of July 1, 1902 did not specify any standards to govern the licensing of biological products (which, under the Act, was the ultimate responsibility of the Secretary of the Treasury).[10] The Act simply provided that "the Surgeon-General of the Army, the Surgeon-General

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[10] For 46 years, the biologics control program operated under the immediate supervision of the director of the Hygenic Laboratory and its successor, the National Institutes of Health (NIH). In 1948 it was made a part of the National Microbiological Institute, a unit of NIH. In 1955, the Division of Biologics Standards (DBS) was established within NIH. DBS was then transferred from NIH to the FDA in 1972 and renamed the Bureau of Biologics. See 37 Fed. Reg. 12865 (1972).

of the Navy, and the supervising Surgeon-General of the Marine-Hospital Service, be, and they are hereby, constituted a board with authority, subject to the approval of the Secretary of the Treasury, to promulgate from time to time such rules as may be necessary in the judgment of said board to govern the issue, suspension, and revocation of licenses for the maintenance of establishments for the propagation and preparation of viruses, serums, toxins, antitoxins, and analogous products, applicable to the prevention and cure of diseases of man" (§ 4, 32 Stat. 729). In 1944 Congress offered more specific guidance (42 U.S.C. 262(d)):

> Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations * * *.

Petitioners and the dissent below argue that this statutory language imposes a "non-discretionary" duty on the FDA to *guarantee* compliance by manufacturers with all regulatory standards prior to issuing a license (see Br. 15-16, 19; Pet. App. 25a-26a). This argument is clearly untenable. Section 262 is simply a general mandate to construct a regulatory licensing program. In supporting enactment of the section, the Committee Report to the Public Health Act explained that "Subsection (d) would furnish criteria, not expressed in the present law, to *guide* administrative action in the issuance of licenses." H.R. Rep. 1364, 78th Cong., 2d Sess. 23 (1944) (emphasis added). Congress thus established the general areas—

"safety, purity, and potency"—within which the FDA was to promulgate regulations for biological products.[11] But the precise nature of those regulations and, hence, the standards for safety, purity and potency as well as the manner in which a manufacturer may demonstrate compliance with the standards was left completely to the discretion of the agency. Like the regulatory scheme at issue in *Varig*, the FDA's choice and "implementation of a mechanism for compliance review is plainly discretionary activity of the 'nature and quality' protected by § 2680(a)." *Varig Airlines*, 467 U.S. at 819. The court of appeals therefore correctly concluded that the FDA's statutory instruction to establish standards and police compliance, like the analogous statute considered in *Varig Airlines*, is not "the type of mandate that makes the discretionary function analysis inapplicable" (Pet. App. 20a).

The statute itself therefore does not deny the FDA discretion in determining whether to license Lederle to produce the Sabin vaccine. Petitioners accordingly devote the bulk of their brief to their contention that the regulations promulgated by the FDA create a mandatory, nondiscretionary duty on the part of FDA employees to ensure compliance with the standards contained therein. It is our contention that the FDA regulations governing the oral polio vaccine, like the FAA regulations at issue in *Varig Airlines*, place no such mandatory duty on the regulating agency. In both cases the ultimate burden of compliance rests with the manufacturer, and the regulations create no duty enforceable against the agency by a tort action. We believe that this is demonstrable by reference to the particular regulations in issue (see pp.

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[11] Vaccines are also classified as prescription drugs under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), and are, thus, subject to certain provisions of that Act as well. See, *e.g.*, 21 U.S.C. 351(a)(2)(B) (conformity with current good manufacturing practice).

28-40, *infra*). More generally, however, we submit that the discretionary function exception bars any and all claims against the government for alleged negligence in the implementation of a safety-related regulatory program.

A. The Discretionary Function Exception Bars Claims Against The Government For Alleged Negligence In The Execution Of A Safety-Related Regulatory Program

1. The FTCA waived the sovereign immunity traditionally enjoyed by the United States against tort suits. See 28 U.S.C. 1346(b) and 2674. This waiver of immunity was considered to be a "radical innovation," however, prompting Congress to move cautiously. *Tort Claims Against the United States: Hearings on H.R. 7236 Before Subcomm. No. 1 of the House Comm. on the Judiciary*, 76th Cong., 3d Sess. 22 (1940). Congress only wanted to make the federal government amenable to suit for "ordinary common-law torts." *Dalehite*, 346 U.S. at 28 (footnote omitted). The legislative history of the FTCA, therefore, is substantially devoted to discussions regarding the need to supply a judicial remedy for automobile accidents involving government employees who drive negligently in the course of their employment.[12] See *Kosak* v. *United States*, 465 U.S. 848, 855 (1984)

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[12] See, *e.g.*, 67 Cong. Rec. 11092, 11100 (1926) (remarks of Reps. Celler, Underhill); 69 Cong. Rec. 2192, 3118 (1928) (remarks of Reps. Lozier, Box); *General Tort Bill: Hearings Before a Subcomm. of the House Comm. on Claims*, 72d Cong., 1st Sess. 17 (1932); *Tort Claims Against the United States: Hearings on H.R. 7236 Before Subcomm. No. 1 of the House Comm. on the Judiciary*, 76th Cong., 3d Sess. 16 (1940); *Tort Claims Against the United States: Hearings on S. 2690 Before a Subcomm. of the Senate Comm. on the Judiciary*, 76th Cong., 3d Sess. 27-28 (1940); *Tort Claims: Hearings on H.R. 5373 and H.R. 6463 Before the House Comm. on the Judiciary*, 77th Cong., 2d Sess. (1942); H.R. Rep. 2245, 77th Cong., 2d Sess. 10 (1942); H.R. Rep. 1287, 79th Cong., 1st Sess. 5 (1945); S. Rep. 1400, 79th Cong., 2d Sess. 31 (1946). The Federal

(footnote omitted) ("One of the principal purposes of the Federal Tort Claims Act was to waive the Government's immunity from liability for injuries resulting from auto accidents in which employees of the Postal Service were at fault.").

Congress did not intend to extend the FTCA to suits against the United States based on "that class of tort on the part of the Government which has to do with a governmental function, so to speak." 86 Cong. Rec. 12021 (1940) (remarks of Rep. Gwynne). Accordingly, Congress placed a number of significant limitations on the types of tort suits that could be brought against the United States. See 28 U.S.C. 2680(a)-(n). "One only need read § 2680 in its entirety to conclude that Congress exercised care to protect the Government from claims, however negligently caused, that affected the governmental functions." *Dalehite*, 346 U.S. at 32. See *Kosak* v. *United States*, 465 U.S. at 858 (one of the principal objectives of the enumerated exceptions in Section 2680 was "ensuring that 'certain governmental activities' not be disrupted by the threat of damages suits").[13]

The most important (see H.R. Rep. 1287, 79th Cong., 1st Sess. 5-6 (1945)) of the limitations on the types of torts suits that may be brought against the United States is that embodied in 28 U.S.C. 2680(a), barring actions "based upon the exercise or performance or the

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Tort Claims Act was adopted in 1946 after more than 20 years of congressional consideration. This Court has recognized that legislative statements made with regard to earlier versions of the FTCA are useful in understanding the meaning of the Act as eventually passed. *Varig Airlines*, 467 U.S. at 808-810; *Dalehite*, 346 U.S. at 26-30.

[13] Comparable, and overlapping, protection against damage liability for engaging in core governmental activities was provided by Congress in 28 U.S.C. 2674, which states that the United States may be liable only "in the same manner and to the same extent as a private individual under like circumstances."

failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government, whether or not the discretion involved be abused." This "discretionary function exception," as it is commonly called, "marks the boundary between Congress' willingness to impose tort liability upon the United States and its desire to protect certain governmental activities from exposure to suit by private individuals." *Varig Airlines*, 467 U.S. at 808.

The boundary is not always clearcut. Where direct government conduct is in issue—as where the government produces a product (*e.g.*, a bridge built by the Army Corps of Engineers) or provides a service (*e.g.*, fire fighting by the Forest Service), the negligent performance of that conduct may bring about injuries that would be actionable under state law if similarly caused by a private person. Where such actions flow from discretionary policy judgments, however, they are immune from FTCA attack under the discretionary function exception. *Dalehite*, 346 U.S. at 35-36. The precise limits of that protection are not susceptible to easy definition, and this Court has generally avoided speaking in broad terms. *Varig Airlines*, 467 U.S. at 813; *Dalehite*, 346 U.S. at 35-36.

The Court has, however, indicated that where the government is not the primary actor, but acts as a regulator of private conduct, demanding compliance with regulatory standards, the discretionary function exception precludes liability altogether. In *Dalehite*, the Court referred to Section 2680(a) simply as "the governmental regulatory function exception from suits" (346 U.S. at 26). The dissent in *Dalehite* was even more emphatic in stressing that "what was meant [by the exception] is the type of discretion which government agencies exercise in regulating private individuals" (346 U.S. at 58 n.12 (Jackson, J., dissenting)). And in *Varig Airlines*, 467 U.S. at 813-814, the Court noted that "whatever else the discretionary function exception

may include, it plainly was intended to encompass the discretionary acts of the Government acting in its role as a regulator of the conduct of private individuals." [14]

Indeed, protection for regulatory activities seems to have been the prime motivation of Congress in creating this exception. The FTCA was the product of more than two dozen different bills introduced since 1923. See *United States* v. *Spelar*, 338 U.S. 217, 219-220 (1949). Many of the earlier bills contained specific exceptions from liability that "were couched in terms of specific spheres of federal activity, such as postal service, the activities of the Securities and Exchange Commission, or the collection of taxes." *Dalehite*, 346 U.S. at 26 (footnote omitted). See, *e.g.*, Section 303(7) of S. 2690, 76th Cong., 1st Sess. (1939) and Section 303(7) of H.R. 5299, 77th Cong., 1st Sess. (1941) (exempting claims arising from enforcement activities of the Federal Trade Commission and the Securities Exchange Commission). The 77th Congress—in whose work the meaning of the exception "shows most clearly" (*Dalehite*, 346 U.S. at 26)—removed the exemptions granted to specific agencies and expanded the exception to include all discretionary functions. *Varig Airlines*, 467 U.S. at 809.

[14] Petitioners read this sentence (Br. 29-30) as a mere tautology, stating that regulatory acts are covered by the discretionary function exception whenever they are discretionary. But there is no reason to think that the Court intended to add nothing by this sentence. Indeed, as support for the proposition that regulation is inherently a discretionary function, the Court in *Varig* noted that "[e]ven the dissenters in *Dalehite* read the legislative history of the discretionary function exception as protecting 'that type of discretion which government agencies exercise in regulating private individuals.'" 467 U.S. at 814 n.11 (quoting *Dalehite*, 346 U.S. at 58 n.12 (Jackson, J., dissenting)). Furthermore, petitioners' reading is belied by the very next sentence, in which the Court stressed that "[t]ime and again the legislative history refers to the acts of regulatory agencies as examples of those covered by the exception * * *." See also 467 U.S. at 814 n.11 (noting the legislative history's "emphasis upon protection for regulatory activities").

Congress made the change with the declared intent to bar all claims against federal agencies growing out of their regulatory activities. "It was considered unnecessary to except by name such agencies as the Federal Trade Commission and the Securities and Exchange Commission, as had earlier bills, because the language of the discretionary function exception would 'exemp[t] from the act claims against Federal agencies *growing out of their regulatory activities.*'" *Varig Airlines*, 467 U.S. at 810 (quoting from Staff of the House Comm. on the Judiciary, 77th Cong., 2d Sess., *Federal Tort Claims Act, Memorandum, With Appendices, Explanatory of Comm. Print of H.R. 5373*, at 8 (Comm. Print 1942) (emphasis added by Court)).

The rationale for this protection for regulatory functions is two-fold. First, the actions of a government agency in enforcing health and safety legislation pursuant to a program of inspection and licensure have no counterpart in the private sector. Unlike private testing laboratories, which certify the quality of a product at the request and for the benefit of a particular consumer,[15] the government inspects and licenses or certifies for the purpose of protecting the general public by eliminating defective or dangerous instrumentalities from the channels of interstate commerce. Thus, government regulation of private industry is precisely the sort

[15] See generally Note, *Liability of Certifiers of Quality to Ultimate Consumers*, 36 Notre Dame Law. 176, 183 (1961); Note, *Tort Liability of Independent Testing Agencies*, 22 Rutgers L. Rev. 299, 325-326 (1968); Note, *Liability of a Testing Company to Third Parties*, 1964 Wash. U.L.Q. 77, 96-97. Some states have concluded that such laboratories may be liable for negligently certifying the safety of a product. See, *e.g.*, *Hanberry* v. *Hearst Corp.*, 276 Cal. App. 2d 680, 683, 81 Cal. Rptr. 519, 521 (1969). The basis for such liability, however, is negligent misrepresentation, which is expressly excluded from the waiver of sovereign immunity in 28 U.S.C. 2680(h). See *United States* v. *Neustadt*, 366 U.S. 696 (1961).

of core governmental function for which Congress expressly intended to preserve immunity.

Second, the potential liability of the United States for failure to uncover defects or improprieties pursuant to regulatory inspections is staggering. Numerous agencies of the federal government have inspection and/or licensing authority and virtually every business that engages in interstate commerce is subject to some form of federally-administered licensing or certification requirement. To name just a few, the Nuclear Regulatory Commission inspects nuclear reactors (42 U.S.C. 2201(*o*)), the FDA inspects and certifies the safety of food as well as drugs (21 U.S.C. 374), the Federal Deposit Insurance Corporation inspects the financial records of federally-insured banks (12 U.S.C. 1817), the Occupational Safety and Health Administration inspects the safety and health conditions of most work environments (29 U.S.C. 657), and the Mine Safety and Health Administration inspects the safety and health conditions of mines (30 U.S.C. 813).[16] It is implausible in the extreme that Con-

[16] Of course, the list in the text only touches the surface. A cursory examination of the regulatory activities of several government agencies reveals an extraordinary array of inspection and licensing/certification activities. See, *e.g.*, 42 U.S.C. 1472 (Farmers Home Administration inspects homes built with financial assistance provided by the agency); 7 U.S.C. 77 (Department of Agriculture inspects poultry products); 21 U.S.C. 603(a) (Department of Agriculture inspects "all cattle, sheep, swine, goats, horses, mules and other equines" before slaughtering, packing or meat-canning); 7 U.S.C. 150ff (Department of Agriculture inspects for plant pests persons or articles transported into this country); 21 U.S.C. 693 (Department of Agriculture inspects and certifies dairy products intended for export); 33 U.S.C. 1318 (Environmental Protection Agency inspects premises where work with chemical substances is performed); 7 U.S.C. 136g (Environmental Protection Agency inspects establishments where pesticides are distributed or sold); 42 U.S.C. (& Supp. III) 6927 (Environmental Protection Agency inspects hazardous waste facilities); 45 U.S.C. 23 (Department of Transportation inspects locomotives); 15 U.S.C. 1401 (Department of Transportation inspects facilities manufacturing or introducing motor vehicles into commerce, see 49 C.F.R. 554.1 *et seq.*); 33 U.S.C. 1512 (Department of Transportation inspects deepwater ports); 33 U.S.C. 467a (Department of Army inspects dams); 38 U.S.C. 642 (Veterans Administration inspects state nursing care homes); 18 U.S.C. (Supp. IV) 923(g) (Department of Treasury inspects firearms or ammunition kept by importers, manufacturers, dealers and collectors); 21 U.S.C. 44 (Department of Health and Human Services inspects teas entering the United States); 15 U.S.C. 2065 (Consumer Product Safety Commission inspects establishments manufacturing, holding or transporting consumer products in commerce, see 16 C.F.R. 118.1 *et seq.* (1982), 16 C.F.R. 1605.1 *et seq.*); and 42 U.S.C. 5413 (Department of Housing and Urban Development inspects the construction of mobile homes).

gress, while enacting the FTCA with an intention to proceed cautiously and protect from suit certain core governmental functions, meant to waive sovereign immunity for claims based on such administrative inspection and licensing activities.[17]

2. In *Varig Airlines*, the plaintiffs sought to hold the United States liable for alleged negligence of the FAA in inspecting airplanes to check compliance with regulatory standards. This Court held that the FAA's program of conducting safety inspections, with the primary burden placed on the manufacturer to ensure compliance, "falls squarely within the discretionary function exception" (467 U.S. at 820). "By fashioning an exception for discretionary governmental functions," the Court stated, "including regulatory activities, Congress took 'steps to protect the Government from liability that would seriously handicap efficient government operations.'" *Id.* at 814 (quoting *United States* v. *Muniz*, 374 U.S. 150, 163 (1963)).

The principal lesson of *Varig Airlines* is that federal regulatory agencies have "a statutory duty to *promote*

[17] Needless to say, not a word in the voluminous legislative history of the FTCA supports such a result. Compare *Muniz*, 374 U.S. at 153-158.

safety" in the industries they regulate, "not to insure it" (467 U.S. at 821 (emphasis in original)). Most courts have heeded this Court's injunction not to turn agency efforts to enhance safety into government insurance of regulated industries.[18] Several cases decided after *Varig Airlines*, however, have imposed liability on the govern-

[18] See, *e.g.*, *Barnson* v. *United States*, 816 F.2d 549 (10th Cir. 1987) (alleged failure of Public Health Service and AEC to warn uranium miners of, and protect them against, radiation hazards), cert. denied, No. 87-104 (Oct. 13, 1987); *Bacon* v. *United States*, 810 F.2d 827 (8th Cir. 1987) (alleged failure of HUD and EPA to warn of dioxin levels during repair of roads at Times Beach under federal block grant); *Merklin* v. *United States*, 788 F.2d 172 (3d Cir. 1986) (AEC inspectors' alleged failure to warn uranium processing plant employees of health hazards discovered during AEC inspections); *Cunningham* v. *United States*, 786 F.2d 1445 (9th Cir. 1986) (alleged failure of OSHA to exercise reasonable care in conducting plant inspections); *Wendler* v. *United States*, 782 F.2d 853 (10th Cir. 1985) (FAA emergency suspension of commercial pilot's certificate), cert. denied, 476 U.S. 112 (1986); *Begay* v. *United States*, 768 F.2d 1059 (9th Cir. 1985) (alleged failure by federal agencies to warn of dangers of uranium mining); *Cisco* v. *United States*, 768 F.2d 788 (7th Cir. 1985) (EPA's alleged failure to warn that dirt contaminated with dioxin had been used in residential land fill); *Baxley* v. *United States*, 767 F.2d 1095 (4th Cir. 1985) (FAA's allegedly negligent decision not to regulate or inspect ultralite aircraft); *Shuman* v. *United States*, 765 F.2d 283 (1st Cir. 1985) (alleged negligence by Navy in not controlling use and handling of asbestos by contractor); *Russell* v. *United States*, 763 F.2d 786 (10th Cir. 1985) (alleged negligence by MSHA in inspecting coal mine); *Hylin* v. *United States*, 755 F.2d 551 (7th Cir. 1985) (mine inspectors' alleged failure fully to inspect clay mine); *Feyers* v. *United States*, 749 F.2d 1222 (6th Cir. 1984) (Army's allegedly negligent failure to inspect contractor's operation of government-owned railyard), cert. denied, 471 U.S. 1125 (1985); *General Public Utilities Corp.* v. *United States*, 745 F.2d 239 (3d Cir. 1984) (NRC's alleged failure to warn of possible equipment defects at Three Mile Island nuclear facility), cert. denied, 469 U.S. 1228 (1985); *Natural Gas Pipeline Co.* v. *United States*, 742 F.2d 502 (9th Cir. 1984) (alleged negligence in FAA inspection and issuance of certificates for aircraft).

ment for negligence in conducting safety compliance checks. See *Collins* v. *United States*, 783 F.2d 1225 (5th Cir. 1986) (decision by Mine Safety and Health Administration to rescind an "Imminent Danger Order" and not to reclassify mine as "gassy" after inspection revealed high methane levels); *National Carriers, Inc.* v. *United States*, 755 F.2d 675 (8th Cir. 1985) (failure of meat inspector to require condemnation, tagging and separation of contaminated beef); *McMichael* v. *United States*, 751 F.2d 303 (8th Cir. 1985) (failure of Defense Department inspectors to enforce safety requirements on defense contractor). These courts distinguished *Varig Airlines* because the inspectors in question had no discretion not "to enforce the detected violations of the safety requirements" (*McMichael*, 751 F.2d at 307; see *Collins*, 783 F.2d at 1230-1231).

Petitioners argue (Br. 9, 13-14), in reliance on such cases, that when licensing and inspection activities are governed by mandatory regulations and an agency violates its own regulations in issuing a license or conducting an inspection, then the discretionary function exception does not apply. A regulatory agency is therefore liable as an insurer, petitioners assert, for the harm caused by any product granted a license or any hazard not detected in an inspection because of a failure to follow such "mandatory regulations."

That specific issue was not directly addressed in *Varig Airlines*. But the answer is nonetheless clear. The wording of the regulations does not change their essential nature, which is to promote safety by policing compliance. The operational burden (and, hence, the burden of negligence) remains with private industry. Allegations that the policeman has failed to do his job, however specifically defined, do not change his essential role from that of regulator to that of insurer.[19]

[19] *Hatahley* v. *United States*, 351 U.S. 173 (1956), upon which petitioners rely (Br. 12-13), is not on point. In that case, federal

More specifically, there are three related flaws with petitioners' argument. First, it ignores the wording of the discretionary function exception, which precludes liability whether or not the government has acted negligently by breaching one of its own regulations. Second, it largely eliminates the protection of regulatory functions—thereby frustrating the prime motivation for the discretionary function exception—because tort claims can almost always be couched in terms of mandatory duties left unperformed. Third, contrary to Congress's express intention, it interjects tort considerations into a regulatory agency's fundamental policy decision on how specifically to write its regulations (and, hence, how carefully to regulate private industry) by providing agencies with a strong incentive to avoid clear directives for enforcement personnel.

(i) The applicability of the discretionary function exception is determined by whether the agency *function* in

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agents, "with complete disregard for the property rights" of certain Navajo Indians (351 U.S. at 181), "vigorously prosecuted a campaign to round up and destroy [the Indians'] horses" in an effort to drive them from public land (*id.* at 176). The Court held that these tortious acts by the officials, committed within the scope of their employment, gave rise to an FTCA claim against the United States. The Court further held that these torts could not be excused post hoc by reference to federal regulations governing impoundment of lifestock unlawfully grazing on federal land because the notice procedures provided in those regulations were not observed (*id.* at 180).

The Court in *Hatahley* did not find that actionable torts had been committed *because* federal officials violated federal regulations. Rather, the Court held simply that the otherwise actionable torts of the officials were not excused by the regulations because, as the government conceded, there was no "attempt at any time to comply with" the regulations. 351 U.S. at 180. The government officials in *Hatahley* were not acting as regulators of private conduct, but rather as trespassers, and the Court thus said that no issue concerning the discretionary function exception was presented (*id.* at 181).

question is discretionary. If it is, then the function is protected regardless of allegations of negligence or other wrongful acts. Section 2680(a) contains two separate provisions, presented in the disjunctive. The first half of Section 2680(a) precludes liability for any "act or omission of an employee of the Government, exercising due care, in the execution of a statute or regulation * * *." No similar requirement—of due care in the execution of a statute or regulation—limits the second provision, the discretionary function exception.

The crucial inquiry in any case under the discretionary function exception, therefore, is not whether an agency inspector acted wrongly or negligently. Were that the test, the discretionary function exception would provide little protection, since it is usually the case that individual employees lack discretion to perform negligently or violate agency regulations. But what is at issue is the fundamental character of the function being performed. Licensing, certification and inspection are paradigms of discretionary functions as Congress understood that term. It follows that no liability may attach to those functions despite claims that the employees carrying them out disobeyed agency regulations or were otherwise negligent.[20]

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[20] Congress of course stressed that "the common-law torts of employees of regulatory agencies would be included within the scope of the bill to the same extent as torts of nonregulatory agencies." H.R. Rep. 2245, 77th Cong., 2d Sess. 10 (1942). Thus, the negligent driving of a mine inspector who gets in a car accident on his way to inspect a mine will give rise to liability. But there is an obvious and fundamental difference between driving a car to the site of an inspection and the quintessentially regulatory function of performing the inspection. That latter function is protected by the discretionary function exception whether or not negligently performed, and whether or not the alleged negligence is demonstrated by reference to a violation of agency regulations.

Petitioners here do not argue that the licensing of the Sabin vaccine was negligent in the sense that its benefits do not outweigh its costs.[21] Rather, they are arguing that DBS (the predecessor of FDA's Bureau of Biologics) was negligent per se because DBS failed, in violation of its own regulations, to require submission by the manufacturer of certain qualifying test results prior to licensing the vaccine. If DBS violated its own regulations, then DBS may well have acted wrongly or negligently. But the discretionary function exception shields from liability "both negligence and wrongful acts in the exercise of the discretion." *Dalehite*, 346 U.S. at 33.

(ii) To permit FTCA suits to be brought against regulatory agencies for their licensing, certification and inspection activities whenever it is alleged that a particular licensing or certification decision was reached or a particular inspection conducted in violation of agency regulations would transform the discretionary function exception from a bar to suit into a rule of pleading. Plaintiffs would merely be required to couch their pleadings in terms not of negligence—which is protected by the exception—but in terms of a violation of the regulations governing some employee's actions.

In most cases, it will be possible to break a particular regulatory action down into component parts and identify some element that arguably violates an applicable regulatory requirement. Litigation of the merits of such an assertion—concluding in a finding of liability if the assertion is borne out—would completely defeat the purpose of the discretionary function exception, which was to bar from the outset such challenges to the performance of discretionary governmental functions through the medium of an action in tort. Other remedies exist

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[21] That would be a foolish argument indeed in light of the fact that the Sabin vaccine has all but eliminated polio in the United States.

for a government agency's alleged breach of its statutory and regulatory obligations.[22] "The purpose of the FTCA is to provide individuals with a means of obtaining tort damages from the United States for injuries negligently inflicted by U.S. employees or agents, and it should not be used to solve the entirely separate, modern problem of alleged bureaucratic inaction and ineptitude." *Baxley* v. *United States*, 767 F.2d 1095, 1098 (4th Cir. 1985).

(iii) The injection of a tort remedy as a means of challenging regulatory action would create incentives that are particularly disruptive of certain sorts of regulatory activity. It would motivate agencies to avoid as much as possible regulations imposing mandatory duties on their own employees because such duties might serve as the basis for government tort liability. In many instances, this may greatly impair the effectiveness of the regulatory program.

In view of local pressures to keep mines open, for example, effective protection of the nation's miners may warrant mandatory regulations that direct subordinates to shut down mines or issue citations in certain specifically-defined circumstances. See *Collins* v. *United States*, *supra*. But if the discretionary function exception does not include all such activity within its ambit, regulators will have a significant disincentive to adopt such regulations. And this disincentive will be strongest in areas where such regulation is needed the most, areas in which the danger (and, hence, the potential liability) is greatest.

If licensing, certifications, and inspections are not completely covered by the discretionary function exception, those administering regulatory programs will be faced with the unpalatable choice of avoiding mandatory regulations, and thus rendering their programs less effective,

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[21] The APA, 5 U.S.C. (& Supp. IV) 551 *et seq.*, offers a comprehensive scheme for review of regulatory action.

or accepting the consequences in increased tort liability. Yet the discretionary function exception was specifically designed to permit a regulatory agency to fulfill its mission in the most effective manner without subjecting the United States to tort liability. Whether regulations should be written tightly or loosely, and how an agency may best ensure performance by its own employees and by the industry it regulates, are policy questions that the agency should be able to resolve without fear of damaging tort liability. See *Varig Airlines*, 467 U.S. at 819-820. If the Court's reading of Section 2680(a) causes agency heads to propose regulations that eschew direct governmental testing when such testing would be in the national interest, then the exception is clearly not working as intended.

In sum, we submit that Congress did not intend to expose the United States to monetary liability—essentially as an insurer—in connection with its role in licensing and inspecting private parties who fail to comply with mandatory health and safety requirements. Congress knows how to make the United States an insurer of a regulated industry when it wants to. See Section C, *infra* (discussing the National Vaccine Compensation Act). When it has not done so expressly, an agency cannot turn itself into an insurer of the industry it regulates simply by the wording of its regulations.

B. The FDA Licensing Process Is Indistinguishable From The FAA Certification Process For Purposes Of The Discretionary Function Exception

Even if the Court were to conclude that an agency's alleged violation of its own regulations governing licenses and inspections could give rise to a cause of action under the FTCA, the judgment below should still be affirmed. No violation of the regulations can be made out on the facts alleged by petitioners because the regulations at issue here do not impose mandatory duties on

the FDA.[23] FDA regulations governing the licensing of vaccines, like FAA regulations governing the certification of aircraft, place the primary burden of compliance on the manufacturer. The method, mode and extent of compliance review is left by the regulations to the discretion of FDA. This is true both for the product license issued to Lederle and for the release of the vaccine lot from which petitioner received his dose.

1. *The Product License*

Two sets of regulations govern the licensing of a poliovirus vaccine. First, there are generic regulations applicable to all product licenses (42 C.F.R. 73.1-73.83 (1963); 21 C.F.R. 600.3-601.26, 610.1-610.65).[24] Second, there are specific regulations that set the standards any live, oral poliovirus vaccine must meet (42 C.F.R. 73.110-73.118; 21 C.F.R. 630.10-630.17). The generic regulations provide that "[a] product license shall be issued only upon examination of the product and upon a determination that the product complies with the stand-

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[23] This case was disposed of on the government's motion to dismiss in lieu of an answer. Accordingly, the factual allegations in petitioners' complaint, though they would be hotly contested were the suit to go further, must be taken as true for purposes of this motion. What is certainly not assumed, however—even for purposes of the present litigation—is that the facts as alleged make out a violation of any mandatory regulations governing the FDA. That is a legal question that turns on the proper interpretation of those regulations. See *Varig Airlines*, 467 U.S. at 816-821. Indeed, it is the question decided by the court below. Petitioners are simply wrong in stating, however insistently (Br. 2, 8, 16, 20, 21, 22), that it is "admitted" that FDA violated its regulations.

[24] The first citation is to the regulations in effect at the time DBS licensed Lederle to produce the vaccine. Where the regulations have remained substantially in the same form, a parallel cite is given to the current regulations.

ards prescribed in the regulations" (42 C.F.R. 73.5(a); 21 C.F.R. 601.4(a)).[25]

Petitioners contend (Br. 16) that this provision imposes a mandatory duty that gives "agency employees no authority to exercise policy judgment in determining whether the conditions of licensing were met." However, this regulation does not, any more than the general statute (see 12-14, *supra*), specify either the nature of the "examination" to be conducted by DBS or the procedures to be used by DBS in making a "determination" that the product complies with the regulatory standards.

The regulations do not place any burden on DBS to conduct tests on the proposed product. To the contrary, the burden is squarely on the manufacturer to "submit data derived from laboratory and clinical studies which demonstrate that the manufactured product meets prescribed standards of safety, purity and potency" (42 C.F.R. 73.3; 21 C.F.R. 601.2(a)).[26] What DBS then does with that data—whether it duplicates certain tests, or painstakingly reviews the data for compliance, or simply spotchecks the application—is left to the agency's discretion. The regulations do specifically provide that the Surgeon General, when he deems it advisable "in matters involving the safety, purity and potency of • • • products for which an application for license is

[25] In addition to the product license, manufacturers must also obtain an establishment license (42 C.F.R. 73.2-73.4; 21 C.F.R. 601.1-601.2, 601.10) after passing an inspection demonstrating that the establishment complies with applicable standards relating to personnel, equipment, sterilization, care of lab animals, record keeping and other matters (see 42 C.F.R. 73.35-73.38). No challenge has been made here to the issuance of an establishment license to Lederle.

[26] The manufacturer is also required to designate a "responsible head who shall exercise control of the establishment in all matters relating to compliance with the provisions of this part" (42 C.F.R. 73.35(a); 21 C.F.R. 600.10(a)).

pending," may appoint a special board of three officers to review the "reports of inspection and laboratory examinations, together with any pertinent data the establishment may submit" (42 C.F.R. 73.12). The open-ended review process, of which this procedure is a part, clearly calls for considerable judgment on the part of the agency both in setting the standards and in policing compliance.[27]

Petitioners must therefore look to the specific regulations governing the oral polio vaccine to make their case that DBS violated mandatory regulations in granting Lederle a product license. Accordingly, petitioners allege (Br. 4-5), first, that DBS licensed the poliovirus strain used by Lederle even though "the strain violated the conditions for licensing prescribed in the regulations." Second, petitioners contend (Br. 5-6) that DBS licensed the particular "seed virus" used by Lederle to produce its vaccine without requiring Lederle to show that the "seed

[27] The decision to license a drug involves a determination, based on limited data, that its known benefits outweigh its potential risks. Thus, our level of uncertainty about a drug's unknown or unknowable risks is deemed acceptable at some point and the decision is made to license a drug with specific warnings. FDA Drug approval procedures have long been scrutinized by Congress, and have been found to reflect the highest standards for effectiveness and safety in the world.

Walsh & Klein, *The Conflicting Objectives of Federal and State Tort Law Drug Regulation*, 41 Food Drug Cosm. L.J. 171, 178 (1986). In its list of approved licenses, FDA itself makes clear that "[t]he licenses granted to these establishments for the products listed in this publication do not imply an endorsement of the respective preparations nor do they make the Government a guarantor or insurer of the safety, purity, and potency of such licensed products." FDA, HHS, *Pub. No. 87-9003, Establishments and Products Licensed under Section 351 of the Public Health Service Act* ii (Apr. 1987).

virus" had been subjected to all required testing and complied with all regulatory standards.

Petitioners are confused on both counts. Contrary to their assertions (Br. 4-5), a license is not issued for the original poliovirus strain itself. Nor are seed viruses individually licensed. Rather, a product license is issued to a manufacturer to produce a vaccine using a particular poliovirus strain that has been found to meet the criteria for acceptable strains set out in 42 C.F.R. 73.110 (b)(2) (21 C.F.R. 630.10(b)(2)). The poliovirus strain at issue here, and the only live poliovirus strain found acceptable for use in the United States, is the strain developed by Dr. Sabin. The Sabin strain is not produced by the manufacturer. Rather, it is obtained directly from Dr. Sabin.

Once the manufacturer obtains the original virus strain from Dr. Sabin, it grows a seed virus from that strain. The seed virus is in turn used to produce the monopools from which portions are combined to make up the actual vaccine ingested by the public. But the seed virus is not separately licensed. Rather, manufacturers are simply forbidden by the regulations to use any seed virus without first performing certain prescribed tests to ensure that the neurovirulence of the seed virus "is no greater than that of the * * * Reference Attenuated Poliovirus" distributed by the agency. 42 C.F.R. 73.110 (b)(4); 21 C.F.R. 630.10(b)(4).

Accordingly, petitioners' claims must be slightly recast. They apparently intend to argue that DBS should not have granted Lederle a product license for Orimune because, first (Br. 4), the original Sabin strain never met the criteria for acceptable strains set out in 42 C.F.R. 73.110(b)(2), and, second (Br. 5), a seed virus to be used by Lederle—production seed 45-B-85—"had not been subjected to the neurovirulence testing required by" 42 C.F.R. 73.110(b)(4). Neither allegation, however, supports petitioners' contention that DBS violated a nondiscretionary regulatory requirement.[28]

The Sabin Strain. 42 C.F.R. 73.110(b) establishes "[c]riteria for acceptable strains" of attenuated poliovirus. It provides, inter alia, that "[p]oliovirus strains shall not be used in the manufacture of Poliovirus Vaccine, Live, Oral, unless * * * data are submitted to the Surgeon General which establish that each such strain is free of harmful effect upon administration in the recommended dosage to at least 100,000 people susceptible to poliomyelitis, under circumstances where adequate epidemiological surveillance of neurological illness has been maintained" (42 C.F.R. 73.110(b)(2)).[29] Petitioners allege (Br. 4) that DBS violated this regulation because "[t]he application submitted to DBS demonstrated that the virus strain for which a license was sought *caused* paralysis in the human test population and was not, therefore, 'without harmful effect.'"

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[28] Petitioners also allege (Br. 19) that "[a]fter production seed 45-B-85 was licensed, it demonstrated a change in neurovirulence, triggering the requirement that its license be revoked." As already noted (see note 7, *supra*), this claim is not properly presented. Moreover, the allegation makes no sense since petitioners are wrong in asserting (Br. 5) that "[e]ach production seed must be individually licensed." But those problems aside, it is clear from the regulations that the Surgeon General need only "recommend" revocation of a product license if "he finds, after notice and opportunity for hearing, that * * * the product for which the license has been issued, fails to conform to the standards in the regulations * * *" (42 C.F.R. 73.9; 21 C.F.R. 601.5). The Surgeon General's decision whether or not to institute such revocation proceedings is a classic exercise of enforcement discretion. *Heckler* v. *Chaney*, 470 U.S. 821 (1985).

[29] The current regulation (21 C.F.R. 630.10(b)(2)) differs from that in effect at the time of the events in issue only in the identity of the official to whom such data must be submitted (the Director, Office of Biologics Research and Review) and the number of persons tested (one million).

Even assuming, *arguendo*, that this regulation constitutes a mandatory direction to the Surgeon General not to grant a license without first receiving data qualifying the strain (rather than, as the words expressly state, a direction to the manufacturer not to "use[]" a strain for which such data have not been "submitted"), there is a major flaw in petitioners' argument. The Sabin strain was found acceptable for use in the United States based on data reviewed by a specially appointed committee of scientists eight months before the regulation in question (which was designed to state the requirements any *new* strain would have to meet) was promulgated and almost three years before Lederle was licensed to produce a vaccine using that strain. See *Polio Vaccines: Hearings Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 87th Cong., 1st Sess. 346 (1961) [hereinafter *Hearings*] (statement of Surgeon General Burney). Under these circumstances, new data on the Sabin strain clearly were not required by the regulations.

In June 1958, Surgeon General Burney appointed a committee of six experts to examine the data available from field and laboratory studies on live poliovirus vaccine, recommend an acceptable strain for use in such a vaccine, and propose licensing requirements. See *Hearings* 328 (first report of the Public Health Service Ad Hoc Committee on Live Poliovirus Vaccine). At that time, three different strains of live virus had been developed and were being tested in vaccines throughout the world: the Sabin strain, the Cox strain and the Koprowski strain. Based on field experience with all the candidate strains, on August 19, 1960, the Committee recommended that the Sabin Strain, Types I, II and III (corresponding to the three types of the polio virus) be selected for use in the United States. In world-wide tests

over 100 million people had received vaccines produced from the Sabin strain without significant adverse effects. See *id.* at 36 (statement of Dr. Murray); *id.* at 332 (second report of the Public Health Service Ad Hoc Committee on Live Poliovirus Vaccine) ("No evidence had been reported to indicate that any of these vaccines produced any harm to these individuals to whom they were administered").[30] Accordingly, on August 24, 1960, Surgeon General Burney announced that the Sabin strain had been found "suitable for use in the United States." *Id.* at 346 (statement of Surgeon General Burney).

Dr. Roderick Murray, the Director of DBS, was a member of the Committee. The Committee worked closely with DBS in drafting regulations to govern the licensing of the live poliovirus vaccine. Although the Sabin strain alone had been found acceptable among the three candidates then known, DBS did not foreclose, and indeed encouraged, the possibility that a fourth strain would be developed. *Hearings* 347 (statement of Surgeon General Burney). Accordingly, instead of writing regulations that simply approved the Sabin strain for use in vaccines, the Committee drafted generic requirements that any new candidate would have to meet. These requirements were specifically written to reflect the criteria by which the Sabin strain had been evaluated, and which the Committee determined had been met by that strain. See *Hearings* 333 (second Committee Report recommending approval of Sabin strain contains same proposal as finally adopted for judging future strains based on "[f]reedom from harmful effects").[31] Petition-

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[30] The vaccine was also tested without harmful effect on 181,000 persons in Cincinnati in a program directed by Dr. Sabin starting in April 1960. *Hearings* 188, 226 (statement of Dr. Sabin).

[31] On November 23, 1960, a Notice of Proposed Rulemaking was published in the Federal Register. 25 Fed. Reg. 11111-11114. On March 25, 1961, the final regulations were published and became

ers' contention that the Sabin vaccine itself does not meet the criteria drafted with it in mind is thus wholly untenable.[32]

Furthermore, even if the regulations had not been written by a committee of experts to match the data already on hand concerning the Sabin strain, the phrase "without harmful effect" is clearly a wide-open term requiring considerable scientific and policy judgment as to what constitutes an acceptable risk under the circumstances. Petitioners' contention that the Sabin strain is unsafe is an attack on the most fundamental scientific/policy decision made by the Surgeon General on advice of the Committee. In effect, petitioners want a chance to enter the Salk/Sabin debate on the side of Salk and to hold the government liable for coming out the other way. That is precisely the sort of "judicial 'second-guessing' of legislative and administrative decisions grounded in social, economic, and political policy through the medium of an action in tort" that Congress was at pains to prevent. *Varig Airlines*, 467 U.S. at 814.

Seed Virus 45-B-85. Petitioners allege (Br. 5) that DBS should not have issued Lederle a product license for Orimune because a seed virus used by Lederle—production seed 45-B-85—was never "subjected to the neurovirulence testing required by the regulations."[33] Petitioners,

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effective on April 24, 1961. 26 Fed. Reg. 2564-2568. On August 17, 1961, the government issued the first license to manufacture the Sabin live polio vaccine, Type 1, to Pfizer Limited. On June 25, 1963, the government licensed Lederle to manufacture a trivalent live oral polio vaccine using the Sabin strain, Types I, II, and III.

[32] The Sabin strain was used as a "reference strain" by DBS, and is still so used by FDA. Manufacturers are required to obtain the strain from FDA for use as a control in performing required tests. 42 C.F.R. 73.111; 21 C.F.R. 630.14.

[33] In fact, Lederle did not begin using production seed 45-B-85 until 1966, three years after Orimune was licensed. Although Lederle did not have to obtain a new license in order to change its manufacturing process, it did have to perform certain prescribed

however, have ignored the language of the regulations, which do not place any burden on DBS employees to conduct tests themselves on the seed viruses used in the manufacture of the vaccine or to obtain such results from the manufacturer prior either to licensing the product or to approving the use of a particular seed virus. Rather, the poliovirus regulations (like the generic regulations discussed at 29-31, *supra*) are aimed directly at the manufacturer. They state that "[n]o seed virus shall be *used* for the manufacture of poliovirus vaccine unless its neurovirulence in Macaca monkeys is no greater than that of the NIH Reference Attenuated Poliovirus." 42 C.F.R. 73.110(b)(4) (emphasis added); 21 C.F.R. 630.10(b)(4). The regulations further specify in detail the "tests to be performed by the manufacturer" to demonstrate "the neurovirulence of the seed virus" (*ibid.*). "Subsequent and identical neurovirulence tests" must be performed by the manufacturers "upon introduction of a new production seed lot and as often as necessary otherwise to establish to the satisfaction of the Surgeon General that the seed virus strains for vaccine manufacture have maintained their neurovirulence properties" (42 C.F.R. 73.110(b)(5); 21 C.F.R. 630.10(b)(5)). The regulations nowhere purport to limit the discretion of, or impose mandatory duties on, the Surgeon General by specifying what he must do before he can be "satisf[ied]" that a particular seed virus meets the requirements.

As the court of appeals here stated (Pet. App. 18a n.6), in taking issue with the Ninth Circuit's decision in *Baker* v. *United States*, 817 F.2d 560 (1987),[34] "[w]e do

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tests and obtain DBS's approval to begin using the new seed virus. We will assume, therefore, that it is DBS's approval of the seed virus that petitioners are attacking.

[34] In *Baker*, the plaintiff alleged that DBS violated its own regulations when it failed to require submission of test data before making

not agree * * * that the FDA is under a duty to require submission of test data. Rather, the duty to submit test data rests with the manufacturer." The Ninth Circuit inferred from the detail of FDA's safety requirements that the agency had exercised its administrative discretion in favor of exhaustive inspection designed to guarantee the safety of vaccines. But the purpose of the detailed standards is to guide *manufacturers* in producing safe vaccines; the standards do not lessen the FDA's inherent discretion to decide how to allocate its resources in attempting to enforce the regulations or shift the burden to the FDA to guarantee compliance. Accordingly, an alleged failure by the agency to ensure that the manufacturer submitted test results, as required by the regulations, cannot form the basis for an FTCA suit.[35] "When an agency determines the extent to which it will supervise the safety procedures of private individuals, it is exercising discretionary regulatory authority of the most basic kind" (*Varig Airlines*, 467 U.S. at 819-820).

2. *The Lot Release*

Petitioners' final allegation (Br. 6-7, 20-21) is that the FDA wrongfully released the specific lot of vaccine from which Kevan Berkovitz received his dose on May

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its licensing decision. The Ninth Circuit concluded that the agency "may not issue a license for manufacturing poliovirus vaccine unless the relevant test data has been submitted," and that the agency thus has a mandatory duty to require the submission of that data (*id.* at 566). The court was unwilling to apply the discretionary function exception to the plaintiff's allegations of "a negligent failure to obey a mandatory regulatory command" (*ibid.*).

[35] Failure to obtain such data from a manufacturer prior to approval might indicate negligence on the part of the agency, but of course the discretionary function exception shields from liability "both negligence and wrongful acts in the exercise of the discretion" granted to the agency. *Dalehite*, 346 U.S. at 33.

10, 1979. Petitioners acknowledge (Br. 20-21) that the regulations place the burden directly on the manufacturer "to test each vaccine lot for compliance with prescribed neurovirulence criteria and to submit the test results to the agency." They note, however (Br. 21), that the FDA is "empowered" to prevent distribution of a noncomplying lot. Petitioners contend (Br. 7) that the data submitted by the manufacturer concerning the particular vaccine lot in question here revealed excessive neurovirulence and that independent agency tests "confirmed that the vaccine exceeded the regulatory standards."[36] Under these circumstances, petitioners argue,

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[36] A trivalent vaccine such as Orimune is made from portions of monopools of each of the three types of poliovirus, and neurovirulence tests are performed on the individual monopools, not on the vaccine itself, 21 C.F.R. 630.17(b). We assume, therefore, that what petitioners intend to allege is that one of the monopools exceeded the permissible level of neurovirulence.

A related misstatement by petitioners is more significant. On page ten of their statutory appendix, petitioners purport to quote portions of 21 C.F.R. 610.2, concerning "requests for samples and protocols" and release "of any lot of any licensed product." Section 610.2(a), in fact and as quoted, states that the Director of the Bureau of Biologics "may" require submission of test results on a lot and further may, "when deemed necessary for the safety, purity, or potency of the product," notify the manufacturer "not [to] distribute a lot of a product until the lot is released by the Director." 21 C.F.R. 610.2(a) (1978) (the current regulation is identical except for the identity of the agency official). Clearly, this language embodies no mandatory guideline limiting the Director's discretion in deciding either to examine test results or to release a given lot.

Petitioners proceed, however, to set forth language which they refer to as Section 610.2(b), which is in fact drawn from 21 C.F.R. 630.17(b). In its proper context, that language is plainly directed at the manufacturer, indicating tests to be performed by the manufacturer, not by the agency. The mis-labelling of this section places it in a context where it might be misunderstood to impose an obligation on the agency.

the agency had a mandatory duty not to release the noncomplying lot.

As the court of appeals correctly noted (Pet. App. 20a-21a), petitioners are simply arguing that release of the lot, under these circumstances, was negligent or otherwise wrongful. The discretionary function exception, however, shields from liability "both negligence and wrongful acts in the exercise of the discretion." *Dalehite*, 346 U.S. at 33. The crucial point is that the FDA is exercising discretion when it decides to examine test results or to conduct its own tests. Failure to block release of a noncomplying product following such an examination may be an abuse of that discretion—see *ibid.* 346 U.S. at 33 ("The exercise of discretion could not be abused without negligence or a wrongful act")—but Section 2680(a) precludes suit "whether or not the discretion involved be abused."

The FDA should not be held to a higher standard—as a guarantor of compliance—because it elected to do more than "spot-check" compliance. An alternative holding, as the court of appeals noted (Pet. App. 21a), "would inhibit the agency's selection of the mechanism for compliance review" and "[t]his is precisely what *Varig* instructs us not to do." The court of appeals therefore correctly concluded (*ibid.*) "that when the FDA makes the discretionary choice to examine or test samples which it has discretion not to test, it cannot be held liable for subsequent negligence at the operational level in implementing its decision to test." The ultimate responsibility for ensuring that a vaccine complies with regulatory requirements rests with the manufacturer,[37] and FDA does not relieve the manufacturer of, or itself assume, that responsibility however "methodically [FDA] examine[s] test results or test[s] vaccine samples" (Pet. App. 21a).

[37] As already noted note 6, *supra*, petitioners in fact obtained a settlement from Lederle.

C. The National Childhood Vaccine Injury Act Confirms That Congress Did Not Intend For The FDA To Be Held Liable Under the FTCA For Injuries Caused By Vaccines

Nothing in the Public Health Service Act remotely shows a Congressional intent to make the FDA an insurer of vaccines and other drugs, and the FDA has not been delegated any authority to turn itself into such an insurer by the wording of its regulations. Congress knows how to set up an insurance program for a regulated industry when it wants to, and when it does so the program looks very different from an ordinary regulatory scheme. We know that, because in 1986 Congress passed just such a program in the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755.[38]

The Act establishes a National Vaccine Injury Compensation Program applicable to all claims in excess of $1,000 against a vaccine manufacturer or health service provider that administers a vaccine, based on vaccine-related injuries. §§ 2110-2111. Claimants must file an affidavit in Claims Court setting forth the nature of

[38] The 1986 Act had no effective date; rather it was not to become effective until funded. Congress subsequently passed the Vaccine Compensation Amendments of 1987 as part of the Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, 101 Stat. 1330. These amendments made the effective date of the program October 1, 1988. Congress authorized (though it has not yet appropriated) $80 million for each year through 1992 to pay for claims arising before the effective date of the Act. Cases arising after the effective date are to be paid from a Trust Fund funded by an excise tax on certain vaccines. See § 2115(i)-(j) (all citations are to the Act as amended in 1987). The Trust Fund is also subrogated to the rights of claimants up to the amount of compensation paid, so that the Fund can seek reimbursement for negligence by vaccine manufacturers. § 2117. By way of fiscal control, the Act contains strict limitations on the numbers of claims that may be filed in each category, and the program automatically terminates if those numbers are exceeded. § 2184.

their injuries, the date, place and nature of the vaccine taken, and assurances that they have not previously collected any award or settlement of a damage action for the injuries in question. § 2111(c). Hearings are held by a Special Master on the issues of causation and damages, with de novo review by the court. No showing of fault or negligence is required. § 2112. Compensation includes actual and projected unreimbursable expenses that resulted from the vaccine-related injury, such as reasonably necessary medical, remedial, and rehabilitative care, including special education, vocational training, emotional or behavioral therapy, special equipment, and residential and custodial care ($250,000 is awarded for any vaccine-related death). § 2115(a). Actual and projected pain and suffering and emotional distress are also reimbursable in an amount not to exceed $250,000. *Ibid.* The Act also provides for reasonable attorneys' fees. § 2115(e). No punitive damages are permitted. § 2115(d). Those with pending civil actions against a manufacturer or administrator of the vaccine may withdraw them without prejudice and elect to file a petition. § 2111(a)(5)(A). Those, however, who have already received damages awarded either under a judgment of a court or a settlement of such action may not file a petition. § 2111(a)(7).[39]

Once a compensation award is fixed, the claimant may elect either to accept the award or to file a civil action against the manufacturer. § 2121. The Act, however, makes certain changes in state tort law that make such an action more difficult.[40] Thus, the claimant would have

[39] Thus, Kevan Berkovitz is not eligible for the program at all in light of his settlement with Lederle.

[40] For example, a manufacturer cannot be held liable for unavoidable injuries caused by a vaccine that was properly prepared and was accompanied by proper directions and warnings. A vaccine is presumed to have been properly prepared if the manufacturer complied with all FDA requirements. § 2122.

to forego a guaranteed compensation package from the program in order to pursue a more uncertain remedy against the manufacturer of the vaccine. The Act was spurred by a perceived need not only to compensate the rare victims of a program that provides overwhelming benefits to the population generally, but also to protect manufacturers of vaccines from ruinous damage awards so as to ensure the continued availability of those vaccines. Congress wanted to substitute a national insurance program for the vagaries of the tort system in this essential area.[41]

Congress thus provided claimants with a remedy against the United States as a substitute for a tort action against the manufacturer or the provider that administers the vaccine. A crucial premise of this program is that persons injured by vaccines do not already have a tort remedy against the United States for having licensed the vaccine. "Currently," Congress noted (H.R. Rep. 99-908, *supra*, at 6), "vaccine-injured persons can seek recovery for their damages only through the civil tort system or through a settlement arrangement with

[41] H.R. Rep. 99-908, 99th Cong., 2d Sess. Pt. 1, at 4-5 (1986) (program necessary because the great success of vaccines is being threatened by mounting liability costs, which have caused prices to go up and the number of manufacturers to go down). See also Mann, *Mass Immunization Cases: Drug Manufacturers' Liability for Failure to Warn*, 29 Vand. L. Rev. 235 (1976) ("Drug manufacturers have ceased, or are threatening to cease, production of these essential, life-saving vaccines. Consequently, these recoveries threaten the effectiveness of the nation's preventative health care programs and contravene the strong public policy of combating infectious disease through widespread vaccination campaigns.").

The administration, it should be noted, does not believe that the Act as passed will in fact have these salutory effects. The Administration opposed the Act in its current form and offered its own alternative bill, H.R. 4777, that would have established a program for vaccine-related injuries along the lines of current workers' compensation programs.

the vaccine manufacturer." Accordingly, in order to make the program an exclusive remedy for vaccine-related injuries, Congress only barred tort suits against "manufacturers and administrators" of vaccines except pursuant to the terms of the Act. No similar bar was placed on FTCA suits against the United States, presumably because Congress viewed the discretionary function exception as a bar to such suits.[42] For the Court now to overlay this insurance scheme with tort liability under the FTCA would wholly disrupt the Act and undermine Congress's attempt to fund the program with a minimum drain on the public fisc. See note 38, *supra*.

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[42] Thus, in the National Swine Flu Immunization Program of 1976, 42 U.S.C. (1976 ed.) 247b(j)-(*l*), the government, in an earlier effort to provide necessary assurance to drug manufacturers by making lawsuits against the government the exclusive remedy for all actions connected with the Swine Flu Program, accepted all liability "for personal injury or death arising out of the administration of swine flu vaccine." In order to permit such suits, Congress expressly waived the discretionary function exception. 42 U.S.C. (1976 ed.) 247b(k)(2). Similarly, Congress has made the discretionary function exception inapplicable to any "grossly negligent" exercise or performance of a discretionary function by the Consumer Products Safety Commission. 15 U.S.C. 2053(h). Needless to say, waivers of this sort would be unnecessary if Congress thought the United States could be liable under the FTCA for its regulatory activity in licensing products.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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